



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,023	12/30/2004	Magnus Qvist	BJS-1916-80	5081

23117 7590 01/04/2007
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
----------	--------------

1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/520,023

Applicant(s)

QVIST, MAGNUS

Examiner

Robert B. Mondesi

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the amendment filed October 5, 2006.

Status of the claims

Claims 1, 6 and 8-10 are pending. **Claim 9** was previously withdrawn for pertaining to non-elected subject matter; however since the applicants have amended the claim to remove the phrase "use of", the claim now reads on a composition and will be rejoined with **claims 1, 6 and 8-10** drawn to a composition. **Claims 2-5 and 7** are canceled. **Claims 1, 6, 8-10** are presently under examination.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn due to applicants' response in amendment filed October 5, 2006.

Specification

The objection to the specification because of containing sequence disclosures at page 5, lines 8-20 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) and failing to comply with one or more of the requirements of 37 C.F.R. § 1.821 through 1.825 for one or more of the reasons set forth on the attached form "Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequences And/Or Amino Acid Sequence Disclosures" has been withdrawn due to applicants' amendment to the specification in amendment filed October 5, 2006.

The rejection of **claims 1, 6, 8 and 10** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

Art Unit: 1652

matter which applicant regards as the invention has been withdrawn due to applicants' amendment to **claim 1** in amendment filed October 5, 2006.

New Objection(s) and Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/44401 in view of Waite, US Patent No. 4,496,397.

WO 01/44401 discloses a composition comprising an aqueous solution of a bioadhesive polyphenolic protein derived from a byssus-forming mussel, which protein comprises 30-300 amino acids and consists essentially of tandemly linked peptide repeats 3-15 amino acid residues, wherein at least 5% of the amino acid residues of said bioadhesive polyphenolic protein are DOPA (page 4, lines 15-29) that can be used for attaching two surfaces or coating a surface. In examples 1-13, pages 7-17, it is demonstrated and discussed how the composition of the invention is used in a method of attaching two surfaces or coating a surface. For example on page 8, lines 4-11 of WO 01/44401, it is stated that a block of corneal tissue was thereby isolated and removed from the original site and mussel adhesive protein (MAP) was administered into the wound cavity and thereafter where the shortly before removed corneal tissue pieces

Art Unit: 1652

repositioned into the cavity to test for the adhesion and reattachment mediated by the MAP glue.

WO 01/44401 teaches that the useful concentration of the mentioned polyphenolic protein is in the range of 0.1-50 mg/ml (Page 6, lines 29-32).

WO 01/44401 also teaches that at least one of the surfaces to be attached or the surface to be coated is a biological surface (Page 8, lines 5-11).

WO 01/44401 does not teach that the bioadhesive composition is an acidic solution wherein the pH of the said acidic solution is 2.5 or less, wherein the acid solution comprises acetic acid.

Waite teaches that the invention relates generally to polyphenolic proteins. More specifically it is concerned with a new and improved process for purifying and stabilizing catechol-containing proteins and with the stabilized proteinaceous materials obtained thereby (column 1, lines 6-12) and that polyphenolic proteins are unique in their ability to adhere to substrates under the environmentally adverse and turbulent conditions in which the mussels exist (column 1, lines 32-34).

Waite teaches further that polyphenolic proteinaceous bioadhesive is also unusual in its superior strength characteristics, which appear to be comparable to those, achieved by synthetic cyanoacrylates. Since it can be applied to wet surfaces without prior drying, it may be considered to be superior to such adhesives. Further, the polyphenolic protein cures extremely rapidly, is nontoxic, and can be used in very fine or thin films exhibiting a coefficient of expansion similar to biological tissue.

More importantly Waite teaches that in accordance with the method of the invention, it has been found that the polyphenolic proteins can be both further purified and even stabilized under controlled pH conditions without the drastic yield reductions experienced heretofore (column 2, lines 39-42), wherein separated borate complexes containing purified catechol-containing polyphenolic proteins are treated to reduce the pH to about 2.5-4 by dialyzing the supernatant liquid containing the stabilized borate complexes containing purified catechol-containing polyphenolic proteins against a volume of a dilute acetic acid solution to provide purified acidic solution of the catechol containing polyphenolic proteins (column 6, lines 48-50 and column 7, lines 62-67: claims 1 and 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain a bioadhesive composition comprising a polyphenolic protein containing DOPA in an acidic environment using acetic acid wherein the pH of the solution is 2.5 for the advantages of retaining significant quantities of the said polyphenolic proteins for prolonged periods of time for subsequent utilization, as taught by WO 01/44401 and Waite, see Waite at column 2, lines 43-47.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/44401 and Waite, US Patent No. 4,496,397 as applied to **claims 1, 6, 8 and 10** above, and further in view of Deming et al., United States Patent No. 6,506,577.

WO 01/44401 and Waite teach a composition as mentioned above.

WO 01/44401 and Waite do not teach that at least one of the surfaces to be attached or the surfaces to be coated is a non-biological surface.

Art Unit: 1652

Deming et al. teach that the invention relates to adhesive copolymers modeled on bioadhesive proteins secreted by marine organisms. These copolymers are compatible with the metabolism, growth and function of living tissues and/or cells *in vitro* or *in vivo* and, consequently, are suitable for use in a wide variety of biomedical applications (column 1, lines 22-28) and that at least one of the surfaces to be attached or the surfaces to be coated is a non-biological surface (column 16, lines 32-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a bioadhesive polyphenolic protein as mentioned above for attaching two surfaces or coating a surface wherein at least one of the surfaces to be attached or the surface to be coated is a non-biological surface for the advantages that it is possible to precisely control the material aspects of the mentioned adhesive with respect to curing time and adhesive strength which allows for wider biomedical and related commercial usage as taught by WO 01/44401, Waite and Deming et al., see Deming et al. at column 3, lines 11-22.

Conclusion

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 1652

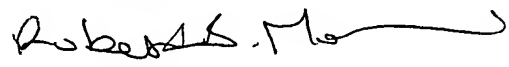
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652


12-18-06